

**DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN
USED ACCORDING TO DIRECTIONS**

2851. Adulteration and misbranding of dextrose in isotonic solution of three chlorides (Ringer's solution), and dextrose in isotonic solution of sodium chloride. U. S. v. Cutter Laboratories, Inc. Plea of nolo contendere. Fine, \$600. (F. D. C. No. 26708. Sample Nos. 350-K, 745-K, 746-K, 10453-K, 10454-K, 16248-K to 16250-K, incl., 16252-K, 24622-K, 36797-K.)

INFORMATION FILED: May 25, 1949, Northern District of California, against Cutter Laboratories, Inc., Berkeley, Calif.

ALLEGED SHIPMENT: Between the approximate dates of October 16, 1947, and March 18, 1948, from the State of California into the States of Georgia, Florida, New Jersey, Illinois, and Washington.

NATURE OF CHARGE: Adulteration, Section 501 (b), the *dextrose in isotonic solution of sodium chloride* purported to be, and was represented as, "Dextrose and Sodium Chloride Injection," a drug the name of which is recognized in the U. S. Pharmacopoeia, and its quality and purity fell below the official standard since it was not sterile but was contaminated with viable micro-organisms; and the difference in quality and purity of the article from the standard was not plainly stated or stated at all on its label.

Adulteration, Section 501 (c), the purity and quality of the *dextrose in isotonic solution of three chlorides (Ringer's solution)* fell below that which it purported and was represented to possess since it purported and was represented to be sterile and suitable and appropriate for intravenous administration, whereas it was not sterile and was not suitable and appropriate for intravenous administration since it was contaminated with viable micro-organisms.

Misbranding, Section 502 (a), the statement "A safe, sterile * * * solution" borne on the labels of the articles was false and misleading since the articles were not sterile and were not safe for use since they were contaminated with viable micro-organisms; and, Section 502 (j), the articles were dangerous to health when used in the dosage and with the frequency and duration suggested in the labeling since the articles were contaminated with viable micro-organisms.

DISPOSITION: June 24, 1949. A plea of nolo contendere having been entered, the court imposed a fine of \$600.

2852. Misbranding of syrup urethane. U. S. v. 9 Jugs, etc. (F. D. C. No. 26859. Sample No. 34272-K.)

LIBEL FILED: March 14, 1949, Northern District of California.

ALLEGED SHIPMENT: On or about October 29 and November 17 and 27, 1948, and January 10, 1949, by Marvin R. Thompson, Inc., from Stamford, Conn.

PRODUCT: 9 1-gallon jugs and 24 1-pint bottles of *syrup urethane* at San Francisco, Calif.

LABEL, IN PART: "Syrup Urethane-M. R. T. * * * Each Teaspoonful (5-cc) contains Urethane 4 Grs. in a Flavored Syrup Base. Directions: 1 teaspoonful every 3 or 4 hours, or as directed by the physician."

NATURE OF CHARGE: Misbranding, Section 502 (j), the article was dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling, namely, "1 teaspoonful every 3 or 4 hours," since administration of 1 teaspoonful every 3 or 4 hours is capable of causing leucopenia.

The article also was in violation of Section 505 (a) since it was a new drug within the meaning of the law, and an application filed pursuant to the law was not effective with respect to the article.

DISPOSITION: November 14, 1949. Marvin R. Thompson, Inc., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the product be released under bond for relabeling under the supervision of the Federal Security Agency.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

2853. Misbranding of benadryl capsules, Dexedrine sulfate tablets, sulfathiazole lozenges, and nembutal and aspirin capsules. U. S. v. Charles E. Prescott (Prescott Drug Store). Plea of nolo contendere. Fine, \$1,000. (F. D. C. No. 26718. Sample Nos. 27056-K, 45894-K, 46419-K, 46422-K.)

INFORMATION FILED: July 8, 1949, Western District of Tennessee, against Charles E. Prescott, trading as the Prescott Drug Store, Memphis, Tenn.

INTERSTATE SHIPMENT: Between the approximate dates of February 17 and December 8, 1948, of one lot of *benadryl capsules*, from St. Louis, Mo.; one lot of *Dexedrine sulfate tablets*, from Philadelphia, Pa.; 1 lot of *sulfathiazole lozenges*, from Indianapolis, Ind.; and 1 lot of *nembutal and aspirin capsules*, from Chicago, Ill.

ALLEGED VIOLATION: On or about January 14, 15, 17, and 18, 1949, and while the articles were being held for sale after shipment in interstate commerce, the defendant caused quantities of the articles to be removed from the bottles in which they had been shipped, and repacked and sold them to various persons without a prescription, which acts of the defendant resulted in the repackaged drugs being misbranded. When shipped in interstate commerce, the articles bore on their labels the prescription legend prescribed by the regulations. The quantities of the articles which were repacked and sold by the defendant were labeled, "Benadryl Capsules 50 Mg. [or "Sulfathiazole Lozenges" or "Nembutal & Aspirin"] Prescott Drugs, Memphis Tennessee" and "Dexedrine Sulfate Tablets."

NATURE OF CHARGE: Misbranding Section 502 (b) (2), the repackaged articles bore no label containing a statement of the quantity of the contents; and, Section 502 (f) (1), they failed to bear labeling containing adequate directions for use.

Further misbranding, Section 502 (b) (1), the *Dexedrine sulfate tablets* bore no label containing the name and place of business of the manufacturer, packer, or distributor. Section 502 (d), the *nembutal and aspirin tablets* were a drug for use by man and contained a chemical derivative of barbituric acid, which derivative has been found by the Administrator of the Federal Security Agency, after investigation, to be, and by regulations designated as, habit-forming; and the labels of the repackaged *nembutal and aspirin capsules* failed to bear the name and quantity or proportion of such derivative and, in juxtaposition therewith, the statement, "Warning—May be habit forming";